DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0421]

Determination That Trilafon Tablets and Three Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the four drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. These are drug products with approved new drug applications (NDAs) to which one or more approved abbreviated new drug applications (ANDAs) refer. This determination means that the approval status of the ANDAs is unaffected by the withdrawal from sale of the reference product.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously

approved under an NDA. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

If a listed drug is withdrawn from sale and there are approved ANDAs that refer to that drug, under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in the table in this document have informed FDA that the drug products have been withdrawn from sale. The drug products in the table are subjects of approved NDAs to which one or more approved ANDAs refer.

NDA No.	Drug	Applicant
10–775	Trilafon (perphenazine) tablets, 2, 4, 8, and 16 milligrams (mg)	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
12–071	Decadron (dexamethasone sodium phosphate) injection, 4 mg/milliliter (mL) and 24 mg/mL	Merck & Co., P.O. Box 4, West Point, GA 19486-0004
14–694	Hexadrol (dexamethasone sodium phosphate) injection, 4 mg/mL and 10 mg/mL	Organon, Inc., 375 Mt. Pleasant Ave., West Orange, NJ 07052

NDA No.	Drug	Applicant
19–304	Tricor (fenofibrate) capsules, 67, 134, and 200 mg	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064-3537

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the withdrawal of these products subject to those NDAs, and accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Dated: September 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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